UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,603	11/21/2003	T. Shantha Raju	P1096R1C1	3279

9157 7590 06/28/2010

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
06/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,603	RAJU, T. SHANTHA	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 25-29* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,25,26,28,29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-6,25,26,28,29 are under consideration.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6,25,26,28,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattes (US Patent 4,859,449) in view of Kumpel et al. and Maras et al. (US Patent 5,834,251). Applicants arguments have been considered and deemed not persuasive.

Mattes teaches therapeutic antibodies with terminal galactose oligosaccharides and the uses/advantages of such antibodies (see abstract, column 6, penultimate paragraph, column 8, last paragraph and claims 1,10,39). G2 antibodies have the maximum number of terminal galactose oligosaccharides. Mattes teaches a kit containing such antibodies (see column 13, first two paragraphs) wherein the antibody is present in a container with a label and wherein the composition present in said kit is a pharmaceutical composition as per recited in the claims. Mattes teaches the use of any IgG antibody (see column 4, third paragraph) wherein IgG1 is one of the art known isotypes of human IgG. Mattes do not teach that the antibodies are of the degree of purity recited in the claims. Kumpel et al. teach human monoclonal antibodies wherein substantially all of the oligosaccharide found on said antibody is G2 (see Table 1, columns 1-3, and page 149, column 1, first incomplete paragraph). The antibody 2B6 disclosed in Table 1 is an IgG1 antibody (see page 144, second column). Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (see columns 12 and 16). Kumpel et al. teach that said enzyme is involved in the production of G2 oligosaccharides (see abstract). A routineer would have used the method of Maras et al. to produce a more highly purified version of the G2

oligosaccharide containing antibody to further characterize the role of said oligosaccharides in effector function and to produce an antibody with even greater effector function. It would have been prima facie obvious to one of ordinary skill in the art to have created the claimed invention because Mattes teaches therapeutic antibodies with terminal galactose oligosaccharides and the uses/advantages of such antibodies whilst Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (e.g. to produce highly pure G2 oligosaccharide glycoproteins). One of ordinary skill in the art would have been motivated to do the aforementioned because Mattes teaches therapeutic antibodies with terminal galactose oligosaccharides and the uses/advantages of such antibodies whilst Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2. A routineer would have used the method of Maras et al. to produce a more highly purified version of the G2 oligosaccharide containing antibody for use in the method taught by Mattes.

Regarding applicants comments about Mattes, claims 1/10/14/16/21 all recite use of antibodies wherein said antibody has " is modified by being further conjugated to, or having *exposed thereon*, a plurality of terminal glycoside residues ...". Thus, Mattes teach use of antibodies wherein the modification is performed by conjugation or *exposure* of the terminal glycoside residues. Thus, the Mattes reference is not limited to use of antibodies with conjugated carbohydrate residues as per applicants comments and Mattes clearly teaches use of antibodies wherein the modification is performed by *exposure* of the terminal glycoside residues. The methods of claims 1/10/14/16/21 all recite methods for clinical use in humans. Regarding applicants comments about neuraminidase, the claims from Mattes recite use of antibodies wherein the modification is performed by *exposure* of the terminal glycoside residues. Said claims are found in an issued US patent and are therefore enabled for the scope of the claimed invention (aka use of antibodies wherein the modification is performed by *exposure* of the

terminal glycoside residues). Regarding applicants comment about methods used for attaching carbohydrates, the claims from Mattes recite use of antibodies wherein the modification is performed by *exposure* of the terminal glycoside residues. Said claims are found in an issued US patent and are therefore enabled for the scope of the claimed invention (aka use of antibodies wherein the modification is performed by *exposure* of the terminal glycoside residues). It would have been prima facie obvious to one of ordinary skill in the art to have created the claimed invention because Mattes teaches therapeutic antibodies with terminal galactose oligosaccharides and the uses/advantages of such antibodies whilst Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (e.g. to produce highly pure G2 oligosaccharide glycoproteins). One of ordinary skill in the art would have been motivated to do the aforementioned because Mattes teaches therapeutic antibodies with terminal galactose oligosaccharides and the uses/advantages of such antibodies whilst Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2. A routineer would have used the method of Maras et al. to produce a more highly purified version of the G2 oligosaccharide containing antibody for use in the method taught by Mattes.

Regarding applicants comments about Kumpel, Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 whilst Mattes teaches *therapeutic antibodies with terminal galactose oligosaccharides and the uses/advantages of such antibodies*. Regarding applicants comments about Maras et al., Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (see columns 12 and 16) whilst Kumpel et al. teach that said enzyme is involved in the production of G2 oligosaccharides (see abstract) and Mattes teaches *therapeutic antibodies with terminal galactose oligosaccharides and the uses/advantages of such antibodies*. In addition, regarding applicants comments about Mattes, the MPEP section 2123 states:

II. NONPREFERRED AND ALTERNATIVE EMBODIMENTS
CONSTITUTE PRIOR ART
Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644